510(k) Summary

As required by 21 CFR 807.92(c)

APR - 8 2011

510(k) Number: K103083

Date Prepared: February 15, 2011

Submitter Information:

Submitter's Name/ Address:	St. Jude Medical 14901 DeVeau Place Minnetonka, MN 55345-2126
Contact Person:	Laura Moen-Ftacek Sr. Regulatory Affairs Specialist Tel: 651-756-2957 Fax: 952-930-9481 lmoen-ftacek@sjm.com

Device Information:

Trade Name:	Agilis™ ES Steerable Introducer
Common Name:	Catheter Introducer/Electrode Recording Catheter
Classification Name:	Catheter Introducer/Electrode Recording Catheter
Class:	Class II, 21 CFR 870.1340, Product Code DYB Class II, 21 CFR 870.1220, Product Code DRF

Predicate Device:

St. Jude Medical Agilis™ NxT Steerable Introducer, Catheter Introducer (K061363/K081645)

St. Jude Medical CPS® Luminary Bi-Deflectable Catheter with Lumen (K052575)

Device Description:

The St. Jude Medical Agilis ES Steerable Introducer consists of a 94cm, 8.5F dilator; a 180cm, 0.032" guidewire; and a 71cm (usable length), 8.5F steerable sheath. It is designed to provide flexible catheter positioning in the cardiac anatomy. The steerable introducer constructed of a polymer shaft that incorporates three platinum/iridium electrodes, the primary use of which is visualization on the EnSite™ System. The electrodes may also be used for recording intracardiac signals and for cardiac stimulation during electrophysiology studies. The steerable introducer is fitted with a hemostasis valve to minimize blood loss during catheter introduction and/or exchange. A sideport with a three-way stopcock is provided for aspiration, fluid infusion, blood sampling, and pressure monitoring. The handle is equipped with a rotating collar to deflect the tip clockwise $\geq$ 180° and counterclockwise $\geq$ 90°. The steerable introducer features distal vent holes to facilitate aspiration and minimize cavitation and a radiopaque tip marker to improve fluoroscopic visualization.

Indications for Use:

The Agilis ES Steerable Introducer is indicated when introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum. The Introducer may be used for recording intracardiac signals and for cardiac stimulation during electrophysiology studies.

Comparison to Predicate Devices:

The Agilis ES Steerable Introducer indication for use is similar to those of the predicate devices. The intended use of the subject device is the same as the predicate devices. In addition, the Agilis ES Steerable Introducer utilizes many of the same materials, design principles and fundamental scientific technology.

Device Characteristic	Subject Device: Agilis ES Steerable Introducer	Agilis NxT Steerable Introducer K061363/ K081645	CPS Luminary Catheter K052575
Indications for Use	The Agilis ES Steerable Introducer is indicated when introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum. The Introducer may be used for recording intracardiac signals and for cardiac stimulation during electrophysiology studies.	The Agilis NxT Steerable Introducer is indicated when introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.	The CPS Luminary Bideflectable Catheter with Lumen is indicated to provide a pathway for delivery and support of transvenous devices and fluids to the coronary sinus and coronary vasculature of the heart. The CPS Luminary Bideflectable Catheter with Lumen can also be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites when minimizing blood loss is essential.
Intended Use	Mapping/Pacing/ Catheter Delivery System	Catheter Delivery System	Mapping/Pacing/ Catheter Delivery System
Handle	Rotary-type Deflection	Rotary-type Deflection	Paddle-type Deflection
Shaft French Size	8.5	8.5	7
Shaft Usable Length	71cm	71cm	80cm
Shaft Curl at Distal Tip	Small, Medium, and Large Curl	Small, Medium, and Large Curl	Large and X-Large Curl
Shaft Deflection	Bi-directional (180°/90°)	Bi-directional (180°/90°)	Bi-directional (small curve/ designated curl)
Electrodes	Three (3) 1mm platinum/iridium electrodes	N/A	Two (2) 1mm platinum electrodes
Dilator French Size	8.5	8.5	N/A
Dilator Length	94cm	94cm	N/A

Dilator Tip Configuration	Curved	Curved	N/A
Guidewire	0.032", fixed core, PTFE coated, 180cm length with 3mm "J" tip	0.032", fixed core, PTFE coated, 180cm length with 3mm "J" tip	Compatible w/ 0.014" - 0.035" guidewire (not included)
Packaging	PVC tray within a sealed LDPE/Tyvek pouch, placed in an SBS paperboard box	PVC tray within a sealed LDPE/Tyvek pouch, placed in an SBS paperboard box	PETG tray and retainer sealed with a Tyvek lid. Tray/lid placed within an outer PETG/Tyvek tray/lid, placed in an SBS paperboard box
Sterilization	EtO SAL 10^{-6}	EtO SAL 10^{-6}	EtO SAL 10^{-6}

Summary of Non-Clinical Testing:

Bench and GLP Animal testing of the Agilis ES Steerable Introducer were performed to support substantial equivalence. Results of the testing demonstrate that the Agilis ES Steerable Introducer meets product specifications and performance requirements.

The following testing, performed or leveraged, has successfully been completed:

Testing performed on the subject device:

- Sterilization Testing
- Shelf Life
- Biocompatibility – Chemical Characterization
- Performance – Bench:
  - Visual
  - Dimensional
    - Electrode spacing
    - Electrode ring/Pebax transition
    - Deflection Angle
  - Electrical
    - Isolation and Continuity
    - Impedance
    - Leakage Current
  - Functional
    - Leak Test
    - Deflection Durability
    - Shaft Kink
    - Insertion/Withdrawal with Short Sheath
    - Shaft Torque Transmission
    - Luer Lock
    - Connector Compatibility
    - Bond Tensile Testing
      - Connector Bond
      - Hub to Mounting Shaft
      - Hub to Shaft Bond
      - Tip/Reflow Bond

- GLP Animal Study – Assessment of the device safety performance and demonstration of the ability to met its intended use.

Testing leverage from the predicate devices:

- Shelf Life
- Packaging
- Biocompatibility
- Performance – Bench:
  - Visual
  - Dimensional
    - Usable Length
    - Inner and Outer Diameter
    - Sheath Tip Holes
  - Functional
    - Insertion Force
    - Radiopacity
    - Hemostasis Seal Leak Test
    - Insertion/Withdrawal with Dilator and Needle
    - Corrosion Resistance
    - Connector Compatibility
    - Bond Tensile Testing
      - Stopcock to Hub
  - Dilator Dimensional Testing
  - Guidewire Dimensional Testing

Clinical Testing: The Agilis ES Steerable Introducer has equivalent clinical performance to the predicate devices. A GLP animal study was conducted to evaluate the subject device for its safety performance and ability to meet its intended use. No clinical testing was required.

Statement of Equivalence:

The Agilis ES Steerable Introducer has similar indications for use and technological characteristics as the predicate devices. Based on this and the design and engineering data provided in the pre-market notification, SJM's Agilis ES Steerable Introducer has been shown to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

St. Jude Medical
c/o Ms. Laura Moen-Ftacek
Sr. Regulatory Affairs Specialist
14901 DeVeau Place
Minnetonka, MN 55345-2126

APR - 8 2011

Re: K103083
Trade/Device Name: Agilis™ ES Steerable Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: March 24, 2011
Received: March 25, 2011

Dear Ms. Moen-Ftacek:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K103083

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vickers

(Division Sign-Off)
Division of Cardiovascular Devices

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